

III. REMARKS

Claims 1-32, 34-48, and 50-72 were pending in this application. Claims 4, 10, 11, 14, 15, and 35 are amended. Upon entry of these amendments, claims 1-32, 34-48, and 50-72 will be pending and under active consideration.

Claims 4 and 10 have been amended to spell out follicle stimulating hormone and human chorionic gonadotropin in their first occurrence, as required by the Examiner. Claims 10 and 11 have been amended to delete the term “until follicular growth is sufficient.” Claims 14 and 15 have been amended at the Examiner’s requirement to contain the phrase “the group consisting of.”

Claim 35 is amended to replace the trademarked name “ARIFLO” with “Cilomilast,” the descriptive name of the drug.

Paragraphs [0003], [0017], [0022], [0042], [0068], [0087], [0133], [0138], Table 1, and [160] of the specification have been amended to correct minor errors as required by the Examiner. No new matter is added in the amendments to the specification.

In view of the foregoing, Applicants respectfully submit that the amendments are fully supported by the instant specification and request entry of the amendments presented herein.

1. Obviousness-Type Double Patenting

The Examiner has provisionally rejected claims 1-7, 14-32, 34, 35, 37-39, 41-47, 50, 51, 54-56, 63, 64, 67, and 69 under the judicially created doctrine of obviousness-type double patenting in view of claims 1-30 of copending App. No. 10/498,639. The Examiner has also rejected claims 1, 2, 3, 32, 34, and 35 under the judicially created doctrine of obviousness-type double patenting in view of claims 2, 3, and 28 of allowed copending Application No. 10/014,812. As the Examiner has noted, neither application has yet issued as a patent. Accordingly, Applicant respectfully defers consideration of the obviousness-type double patenting rejections until the claims of one or both of the applications are patented.

2. 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 10 and 11 under 35 U.S.C. § 112, second paragraph as indefinite with respect to the term “sufficient” in relation to follicular growth. Claims 10 and 11 have been amended to delete the term “until follicular growth is sufficient.” Accordingly,

Applicant respectfully requests that the Examiner's rejection of claims 10 and 11 under 35 U.S.C. § 112, second paragraph be withdrawn.

The Examiner has rejected claim 35 for inclusion of the name "Ariflo." Claim 35 has been amended to replace "Ariflo" with the descriptive name "Cilomilast." Applicant respectfully submits that the Examiner's rejection of claim 35 has been overcome.

3. 35 U.S.C. § 102(e)

The Examiner has rejected claims 1-7, 14-32, 34, 35, 37-42, 44-47, 50, 51, 54, 55-58, 62, and, 63 under 35 U.S.C. § 102(e) as anticipated by Palmer, et al., U.S. Pat. Pub. No. 2002/0065324 ("Palmer"). The Examiner has characterized Palmer as disclosing a method of improving fertility in a female host comprising administration of a non-polypeptide cAMP level modulator to the female host. The Examiner further provides a summary of experimental results from a test of the effect of a PDE inhibitor on ovulation. Applicant respectfully submits that the cited reference fails to provide every element of the rejected claims.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). At page 7 of the Office Action, the Examiner contends that Palmer "describe[s] the effects of a PDE inhibitor on ovulation"(emphasis added). The Examiner further contends that Palmer demonstrates "a PDE inhibitor enhances hCG-stimulated ovulation"(emphasis added). In contrast to the characterization of Palmer, the Examiner contends that the elected claims of the present application are drawn to "a method of stimulating ovarian follicular growth or follicle maturation." *See, e.g.*, Office Action at page 5 (emphasis added). As noted at paragraphs [0003]-[0005] of the Specification, ovarian follicular growth and maturation is distinct from ovulation. By failing to show that Palmer describes a method for stimulating ovarian follicular growth or follicle maturation, Applicant respectfully submits that the Examiner has not made a prima facie case of anticipation. Accordingly, Applicant respectfully submits that the rejection under 35 U.S.C. § 102(e) should be withdrawn.

4. 35 U.S.C. § 103

a. Rejection over Palmer in view of Bowman

The Examiner has rejected claims 1-11, 14-32, 34, 35, 37-47, 50-59, and 62-65 under 35 U.S.C. § 103(a) as obvious over Palmer in view of Bowman. The Examiner has characterized Bowman as disclosing the “temporal pattern and concentration of the hormonal changes associated with the menstrual cycle,” which allegedly cures the failure of Palmer to disclose the time during the menstrual cycle during which the compounds should be administered.

Applicant has discussed the deficiencies of Palmer above, and respectfully reiterates that the Examiner has failed to show that Palmer describes the use of a PDE inhibitor in a method for stimulating ovarian follicular growth in a female or a method for increasing follicle maturation. Because Bowman fails to cure the deficiencies of Palmer, the combination of references does not meet the requirements for a prima facie case of obviousness which include, inter alia, that they teach or suggest each and every element of the claimed combination.

b. Rejection over Palmer in view of Barbieri

The Examiner has rejected claims 66-72 under 35 U.S.C. § 103(a) as obvious over Palmer in view of Barbieri. The Examiner has characterized Barbieri as disclosing “ovarian stimulation with exogenous gonadotropins and pituitary suppression with gonadotropin releasing hormone analogues,” which allegedly cures the failure of Palmer to disclose “the suppression of endogenous FSH and LH by the administration of GnRH or an analog thereof to a female.”

Applicant has discussed the deficiencies of Palmer above, and respectfully reiterates that the Examiner has failed to show that Palmer describes the use of a PDE inhibitor in a method for stimulating ovarian follicular growth in a female or a method for increasing follicle maturation. Because Barbieri fails to cure the deficiencies of Palmer, the combination of references does not meet the requirements for a prima facie case of obviousness which include, inter alia, that they teach or suggest each and every element of the claimed combination.

Because neither Bowman nor Barbieri cures the failure of Palmer to describe a method for stimulating ovarian follicular growth in a female or a method for increasing follicle maturation using a PDE inhibitor, Applicant respectfully submits that the rejection under 35 U.S.C. § 103(a) should be withdrawn.

IV. CONCLUSION

Applicants respectfully submit that this reply is fully responsive to the Office Action in compliance with 37 C.F.R. § 1.121. Should the Examiner determine that this reply is insufficient, Applicants respectfully request prompt notification, so that any error or omission may be corrected.

Applicants respectfully submit that the present application is in good and proper order for allowance. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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By:



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